REMARKS

Claims 1-28, 30-63, 65, 66, 69-84 are pending herein.

Claim 29 is cancelled for the reasons to follow. Claim 29 depended from claim 28. In claim 28, the active region is disposed beneath the balloon. Thus, the limitation of claim 29 wherein the balloon is positioned over at least a portion of the active region did not further restrict the scope of claim 28, and claim 29 was improper.

Presently pending claims 7, 8, 14, 17-23, 26, 27, 33, 39-49, 51, 53, 55, 58, 59, 62, 65, 66, 69, 70, and 75-79 are withdrawn from consideration by virtue of applicant's species election.

Rejection of claims 1-6, 9, 12, 13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56, 57, 61, 71, 72, 80 and 84 under 35 U.S.C. 102(e) over Maseda et al. US 6,514,237 (Maseda)

Claims 1-6, 9, 12, 13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56 57, 61, 71, 72, 80 and 84 are rejected under 35 U.S.C 102(e) as being anticipated by Maseda. Applicant respectfully traverses this rejection and its supporting comments.

Applicant respectfully requests that the remarks presented in the response to the first rejection on the merits be incorporated by reference herein. The following remarks emphasize aspects of those remarks and respond to the Examiner's reasons for finding them unconvincing.

Claim 1

Claim 1 is directed to a medical device comprising (a) an elongate body adapted for insertion into a body lumen, said elongate body having distal and proximal ends and an axis; and (b) an active region comprising a *conductive polymer* disposed over the elongate body *such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the active region.*

Applicant's claims, should be interpreted as they would be by one of ordinary skill in the art to whom they are directed in light of the specification and the state of the art. *In re Watson*, 186 U.S.P.Q. 11, 20 (Fed. Cir. 1975). That person of ordinary skill would not have interpreted the present claims as reading on the ion exchange polymer-noble metal composites of the reference.

The Examiner urges that claim 1 is broad enough to all the different categories of electroactive polymers, including those of Maseda. More particularly, the Examiner argues that

ionic exchange polymer-noble metal composites are inherently conductive and can thus be considered to be conductive polymers in a "broad sense." Applicant respectfully disagrees with the Examiner's analysis.

Enclosing H. Sahoo et al., "Actuators based on electroactive polymers," *Current Science,* Vol. 81, No. 7, 10 October 2001, 743-746, Applicant pointed out in the response to the prior Office Action of September 21, 2006 that ionic polymer metal composites and conductive polymer actuators are distinct classes of material in the electroactive polymer art. One of ordinary skill in the art would, therefore, not confuse conductive polymers like those claimed with ionic polymer metal composites like those described in Maseda.

Moreover, claim 1 requires *both* "volumetric expansion" of the "active region" *and* expansion of the medical device in a "radial dimension." As noted previously, mass transfer of ions into and out of conductive polymer material recited in the claims (e.g., transfer from and into an ionically conductive electrolyte medium associated with the conductive polymer) leads to the volumetric expansion or contraction of the polymer. The ion exchange polymer-noble metal composites of the Maseda reference, however, do not expand. They only bend. In particular, it was previously pointed out that when a voltage is applied, an electric field is set up inside the ionic polymer of an ion exchange polymer-noble metal composite causing the ions (e.g., cations) within the polymer, along with associated hydrated water molecules, to move within the polymer towards one of the electrodes (e.g., the cathode), which movement of within the polymer produces a bend in the EAP towards the other electrode (e.g., the anode). Being self contained, such actuators do not undergo volumetric expansion, as do conductive polymers like those presently claimed, rather they undergo deformation in the form of bending.

The Examiner apparently understands this, but claims that Maseda at col. 3, line 54 teaches that ion exchange polymer-noble metal composites are capable of expanding. Actually, this portion of Maseda merely teaches the following: "The activation, via the controller, of the electroactive polymer strands embedded in and/or replacing sections of the flexible probe device may induce movements such as ... expansion..." Nothing in this citation teaches that the composites themselves are capable of expanding.

The Examiner also argues that the Academic Press Dictionary of Science and Technology defines "expansion" as an increase in volume. However, claim 1 is not simply directed to mere "expansion" or even mere "volumetric expansion" which the Examiner might believe embraces

the bending of the ion exchange polymer-noble metal composites of Maseda in certain embodiments (see, e.g., the collection of ion exchange polymer-noble metal composite strips 500, which are constrained from movement on their ends and are said to "expand like a balloon" as disclosed in col. 6 and illustrated in Figs. 5 and 5A of Maseda). Rather claim 1 requires "volumetric expansion *of the active region"* a concept that is neither taught nor suggested by the bending composite strips of Maseda.

Finally, with respect to the quotation from paragraph [0055] of the present specification referred to by the Examiner, the full quote is as follows: "As discussed above, the EAP-containing active region contracts or expands in response to the flow of ions out of, or into, the same. Essentially any electroactive polymer that exhibits contractile or expansile properties may be used in connection with the various active regions of the invention, including those listed above." Thus, the "contractile or expansile properties" being referred to are the contraction or expansion of an EAP-containing active region in response to the flow of ions out of, or into, the same. This portion of the specification is therefore entirely consistent with the language of claim 1 and with applicant's statements. Moreover, based on the design of ion exchange polymer-noble metal composite strips such as those of Maseda, expansion and contraction of this nature would not be possible.

For at least the above reasons, the limitations of claim 1, and the claims dependent thereon (2-27, 69-76 and 80-84), are not met by Maseda.

Claim 28

Claim 28 is directed to a medical device that comprises (a) an elongate body adapted for insertion into a body lumen; (b) a balloon; and (c) *an active region comprising an electroactive polymer disposed over the elongate body and beneath the balloon. The active region is adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state.*

Nothing resembling this device is taught in Maseda. For example, Maseda does not describe a device wherein the active region is adapted to radially advance at least a portion of a balloon when the balloon is in a substantially uninflated state—much less one in which an active region comprising an electroactive polymer is disposed over the elongate body and beneath the balloon.

As previously noted, an advantage of the present invention is that medical devices can be provided in which hydraulic expansion mechanisms are supplemented, thereby allowing these devices to operate efficiently at very small diameters. For example, by radially advancing at least a portion of a balloon outward from a fully crimped state, the balloon enters into a more efficient operating range, where less pressure is required to generate the large strains that are afforded by hydraulic actuation of this type.

The Examiner has responded by stating that Maeda teaches that "a portion of the balloon can be expanded radially because the distal end of the elongate body, which contains electroactive polymer strands over the entire length is positioned beneath the balloon so when the strands beneath the balloon are activated, the balloon can be inflated by miniscule force."

Applicant respectfully traverses this characterization of Maseda. For example, the Examiner's support for this characterization is apparently set forth at pages 2 to 3 of the Office Action, where it is alleged that Maseda describes, inter alia (emphasis in original):

> an active region (composite strands; col. 4, lines 44-48) comprising an electroactive polymer (col. 5, lines 1-19) *disposed over the elongate body and beneath the balloon* (distal end 128 of elongate body 114 which also contains active regions is under balloon 118; col.6, lines 64- col.7, line 1), said active region being adapted to radially advance (col. 3, lines 2-6) at least a portion of the balloon when the balloon is in a substantially un-inflated state (col. 6, lines 45-51).

With respect to the italicized portion of the above quotation, it is noted that the cited text at col.6, lines 64- col.7, line 1 reads as follows (emphasis added): "FIG. 6 illustrates another exemplary embodiment of the present invention. In this exemplary embodiment, the composite strands 600 may be *attached to the end of the distal leg 128 of the balloon 118 of the balloon catheter 110*..." Thus, this text merely teaches that the composite strands can be attached to the end of the distal leg of the balloon (see, e.g., the strands 600 shown attached to the distal leg 128 in Fig. 6B). However, there is a great difference between strands that are *attached to* the distal end of a balloon, and strands that are disposed *over* an elongate body and *beneath* a balloon as claimed.

With respect for the alleged support for an active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially un-inflated state, the Examiner cites col.3, lines 2-6 ("the electroactive polymer strands may be integrated into various segments of the devices such that a section of the device expands in a manner which

mimics a balloon in a balloon catheter or to expand an end of the probe to mimic an anchoring device") and col. 6, lines 45-51 ("When no voltage is applied to the composite strips 500, the outer tubular body 114 holds its normally relaxed position as illustrated in FIG. 5. However, when a predetermined voltage is applied to the composite strips 500 in a controlled manner, via the control module 300, the composite strips 500, which are constrained from movement on their ends, expand like a balloon as illustrated in FIG. 5A.") With respect to the first citation, this sentence is consistent with the various embodiments shown in the drawings of Maseda, and mimicking a balloon has nothing to do with providing *an active region that is adapted to radially advance at least a portion of a balloon* when the balloon is in a substantially un-inflated state as claimed. Similarly the second citation, while teaching that the composite strips can be bent such that they expand in a fashion analogous to a balloon (see Fig. 5A), is remote from an active region that is adapted to radially advance at least a portion of an uninflated balloon.

Maseda does not describe a device wherein the active region is adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state—much less one in which an active region comprising an electroactive polymer is disposed *over* the elongate body and *beneath* the balloon as claimed.

For at least these reasons, it is respectfully submitted that the limitations of claim 28, and claims 29-42 dependent thereon, are not met by Maseda.

Claim 50

Claim 50 is directed to a device comprising: (a) an insertable body adapted for insertion into a body lumen of a patient; (b) a device lumen within said insertable body; (c) an inflatable balloon, the interior of which balloon is in fluid communication with the device lumen, and (d) one or more electrically actuated members disposed along at least a portion of the length of the device lumen. The electrically actuated members, which are adapted to transform at least a portion of the length of the device lumen between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient.

Thus claim 50 requires, inter alia, a device lumen transformable between (i) a radially expanded state and (ii) a radially contracted state, which device lumen is in fluid communication with the interior of an inflatable balloon.

Nothing resembling such a device is taught in Maseda. While Figs. 5 and 5A might arguably illustrate a device "lumen" that is transformable between (i) a radially expanded state and (ii) a radially contracted state, such a lumen is clearly not in fluid communication with the interior of the balloon due to the presence of the slits in the lumen that exist between the circumferentially spaced composite strands 500, which would render balloon inflation impossible.

For evidence of one or more electrically actuated members, which are adapted to transform at least a portion of the length of the device lumen between (i) a radially expanded state and (ii) a radially contracted state in which the insertable body is more readily inserted into the body lumen of the patient, the Examiner references col. 3, lines 2-6 ("the electroactive polymer strands may be integrated into various segments of the devices such that a section of the device expands in a manner which mimics a balloon in a balloon catheter or to expand an end of the probe to mimic an anchoring device".) However, for all described embodiments in which a lumen is arguably radially expanded in a fashion that mimics a balloon, this is accomplished by the use of multiple bendable strands which are circumferentially spaced from one another when actuated (see, e.g., Figs. 5 and 5A). Such a lumen is clearly not placed in fluid communication with the interior of the balloon, due to the presence of the spaces that exist between the circumferentially spaced composite strands 500. There is no possibility of inherency.

For at least these reasons, it is respectfully submitted that the limitations of claim 50, and claims 51-63, 65, 66, 78 and 79 dependent thereon, are not met by Maseda.

Claims 4, 71 and 72

With respect to claim 4, Maseda does not describe a catheter wherein a deformable region is expanded in at least one radial dimension upon volumetric expansion of an active region. See also claim 71 (wherein the deformable region of claim 4 is an elongated flexible material) and claim 72 (wherein the deformable region of claim 4 is an elastic region).

Claims 5 and 36

With respect to pending claims 5 and 36, Maseda does not describe a circumferential *band* (i.e., an annulus). In Figure 3B, a *strand* 308 is wrapped in a *helical manner*. To interpret

the helix formed from a strand as a "band" requires a clear distortion of the language. Thus, the limitations of claims 5 and 36 are not met by Maseda.

Claim 16

With respect to claim 16, Maseda does not describe a catheter wherein one or more active regions are disposed such that, upon expansion of the one or more active regions, at least a portion of the balloon is expanded from a first position to a second position that is radially beyond the first position.

Claim 34

With respect to claim 34, Maseda does not describe a catheter wherein at least a portion of the balloon is radially advanced directly by the volumetric expansion of an active region.

Claim 84

Present claim 84 requires that the active region be disposed *over* an elongate body *and beneath* a balloon. The Examiner has referred to column 5, lines 20-24, and column 6, lines 65-66, neither of which cites discloses anything like that limitation. The first cite discloses that if hydrogels are used, they would be "inserted into chambers in one or more locations in the flexible medical probe device." The second cite refers to Figure 6, where the composite strands may be attached to the end of the distal leg of the balloon. There is, however, a great difference between composites strands *attached to* the distal end of a balloon, and an active region that is disposed over an elongate body and beneath a balloon as claimed. The specification of Maseda does not describe, and the drawings of Maseda do not show, a device having such features.

Thus, the limitations of claims 84 are not met by Maseda.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1-6, 9, 12, 13, 15, 16, 24, 25, 28, 29, 34, 36-38, 50, 54, 56 57, 61, 71, 72, 80 and 84 under 35 U.S.C. 102(e) over Maseda is respectfully requested.

Serial No.: 10/763,825

Rejection of claims 81-83 under 35 USC 102(e) over Couvillon US 6,679,836

Claims 81-83 have been rejected under 35 U.S.C. 102(e) as being anticipated by Couvillon. Applicant respectfully traverses this rejection and its supporting comments.

Claims 81-83 are dependent on independent claim 1 and thus contain all of the limitations of the independent claim.

Claim 1 requires that "the *medical device is expanded in at least one radial dimension* relative to said axis upon volumetric expansion of the active region." Although Couvillon disclose that the electronic polymer actuators (EAPs) themselves may expand, there is no disclosure corresponding to the emphasized limitation of a medical device that expands in at least one radial dimension relative to the axis of the elongate body upon volumetric expansion of an active region. That follows from the placement of the EAPs in the device disclosed by Couvillon, which is different from those disclosed in the present specification. It is the placement disclosed herein and recited expressly in some claims that leads to the emphasized limitation. Thus, not all of the limitations of claims 81-83 are disclosed in the reference, and there is no anticipation. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (Fed. Cir. 1978). Also see MPEP 2131.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 102(e) over Couvillon is respectfully requested.

Rejection of claims 10, 11, 30-32, 35, 52, 60, 63, 73 and 74 under 35 U.S.C. 103(a)

Claims 10, 11, 30-32, 35 52, 60, 63, 73 and 74 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda. This rejection is respectfully traversed.

The fundamental defects of the Maseda reference have been discussed above. Claims 10, 11, 30-32, 35 52, 60, 63, 73 and 74 are patentable for at least the same reasons as the independent claims from which they depend, among other reasons.

The Examiner has not presented any response to applicant's prior remarks concerning this rejection in the response to the first action on the merits.

It bears repetition here that the Examiner has acknowledged that specific limitations have not been "directly" taught. The Examiner's reasoning that the device disclosed by the reference is *capable* of carrying out the functions recited in the present claims or *could* be modified in such

a way as to result in the present claims does not provide the valid criteria for a conclusion of *prima facie* obviousness, i.e., "capable of" and "could be modified" are not the same as "obvious to." See *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (BPAI 1993).

Claim 10

The limitation of claim 10, in which the active region of claim 1 is disposed in a recess formed in the elongate body, wherein the recess is a circumferential recess, is neither taught nor suggested by the prior art.

Claim 30

The limitation of claim 30, in which the active region of claim 28 is adapted to radially advance a proximal portion of the balloon, is neither taught nor suggested by the prior art.

Claim 31

The limitation of claim 31, in which the active region of claim 28 is adapted to radially advance proximal and distal portions of the balloon, is neither taught nor suggested by the prior art.

Claim 32

The limitation of claim 32, in which the active region of claim 28 is adapted to radially advance proximal, central and distal portions of the balloon, is neither taught nor suggested by the prior art.

Serial No.: 10/763,825

Claim 35

It is noted that the mesh material of Maseda is part of the active material in a particular form and location to carry out a particular function in front of the balloon. Thus it can not "perform the function of a passive deformable region" as stated by the Examiner.

Claims 60, 73 and 74

With regard to claims 60, 73 and 74, a disclosure of "various other configurations" does not make any specific undisclosed configuration obvious, absent some explanation based on logic and sound scientific reasoning. *Ex parte Levengood supra*. On this record there is no such explanation.

Reconsideration and withdrawal of the above rejection under 35 U.S.C. 103(a) are respectfully requested.

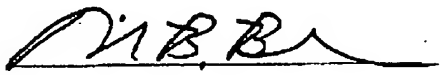
CONCLUSION

In light of the foregoing remarks, it is believed that all rejections of record have been obviated, and allowance of this application is respectfully requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

FEES

The Office is authorized to charge any fees that are due as a result of this Response, to the undersigned attorney's PTO Deposit Account #50-1047.

Respectfully submitted,



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